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Indian Standard
SPECIFICATION FOR ENDOTRACHEAL TUBES (RUBBER)

(First Reprint SEPTEMBER 1989)

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NEW DELHI 110002

Gr 3 *September* 1972

Indian Standard
SPECIFICATION FOR ENDOTRACHEAL TUBES (RUBBER)

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Secretary

Shri D. K. Agrawal

Deputy Director (Consr Prod & Med Instr), ISI

(*Continued on page* 2)

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*Shri H. Ghosh was the Chairman for the meeting in which this standard was finalized.

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(*Continued from page* 1)

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Indian Standard
SPECIFICATION FOR ENDOTRACHEAL TUBES (RUBBER)

0. FOREWORD

0.1 This Indian Standard was adopted by the Indian Standards Institution on 10 March 1972, after the draft finalized by the Anaesthesia, Resuscitation and Allied Equipment Sectional Committee had been approved by the Consumer Products and Medical Instruments Division Council.

0.2 Endotracheal tubes are commonly used by anaesthetists and are essential to the safety of the patients. In this specification an attempt has been made to regulate the quality and thickness of the rubber used.

0.3 In the preparation of this specification, considerable assistance has been derived from the following:

Doc : ISO/TC 121 (Secretariat-42) 61 ISO draft proposal for endotracheal tubes. International Organization for Standardization.

BS 3487-1962 Specification for endotracheal tubes. British Standards Institution.

Z79.1-1960 Specification for endotracheal tubes. American Standards Association.

0.4 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS : 2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1. SCOPE

1.1 This standard deals with the basic requirements for oral and nasal endotracheal tubes and cuffs.

2. NOMENCLATURE

2.1 For the purpose of this standard, the nomenclature given below and

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*Rules for rounding off numerical values (*revised*).

in Fig. 1 and 2 shall apply.

2.1.1 *Endotracheal Tube* — A tube used to convey gases or vapours to and from the trachea.

2.1.2 *Oral Endotracheal Tube* — Endotracheal tube for insertion through the mouth into the trachea.

2.1.3 *Nasal Endotracheal Tube* — Endotracheal tube for insertion through the nose into the trachea.

2.1.4 *Patient End* — End of the endotracheal tube which is intended to be inserted into the trachea of a patient.

2.1.5 *Machine End* — End of the endotracheal tube which is intended to project from the patient.

2.1.6 *Bevel* — Oblique opening at the patient end of the endotracheal tube.

2.1.7 *Angle of Bevel* — Angle between the longitudinal axis and the bevel of the endotracheal tube.

2.1.8 *Cuff* — Inflatable sleeve present near the patient end of the endotracheal tube to provide an effective fit between the tube and the trachea.

2.1.9 *Bonded Cuff* — Permanently attached cuff.

2.1.10 *Slip-On Tracheal Cuff* — Cuff which is not permanently attached.

2.1.11 *Pilot Balloon* — Small balloon which may be fitted to the inflating tube to indicate inflation of the cuff.

3. MATERIALS

3.1 The endotracheal tube shall be made of natural rubber compound. The compound shall possess the physical properties as given in Table 1.

3.2 The material shall be non-toxic, compatible with human tissue.

3.3 Unless designated as disposable, endotracheal tubes shall be reasonably resistant to deterioration by methods of cleaning, disinfection and sterilization as recommended by the manufacturer or the supplier. It is desirable that such tubes should withstand accepted methods of steam sterilization. The recommended method or methods of sterilization should not produce changes in the material which will render the endotracheal tube incompatible with human tissue.

3.4 Endotracheal tubes should be reasonably resistant to anaesthetic vapours and gases.

4. DIMENSIONS

4.1 The dimensions of the endotracheal tube shall be in accordance with Table 2 and Fig. 1 and 2 (*see also* **4.2** to **4.8**).

AMENDMENT NO. 1 NOVEMBER 1984
TO
IS:6581-1972 SPECIFICATION FOR ENDOTRACHEAL TUBES (RUBBER)

Addenda

(*Page 4, clause 3.4*) - Add a new clause as follows:

'3.5 The endotracheal tubes shall be red in colour.'

(*Page 10, clause 8*) - Add new clause as follows:

'9. TEST

9.1 The air inflated pilot balloon and endotracheal tube shall not show any sign of leakage when tested under a pressure of 600 mm of water column.'

(CPDC 13)

Reprography Unit, BIS, New Delhi, India

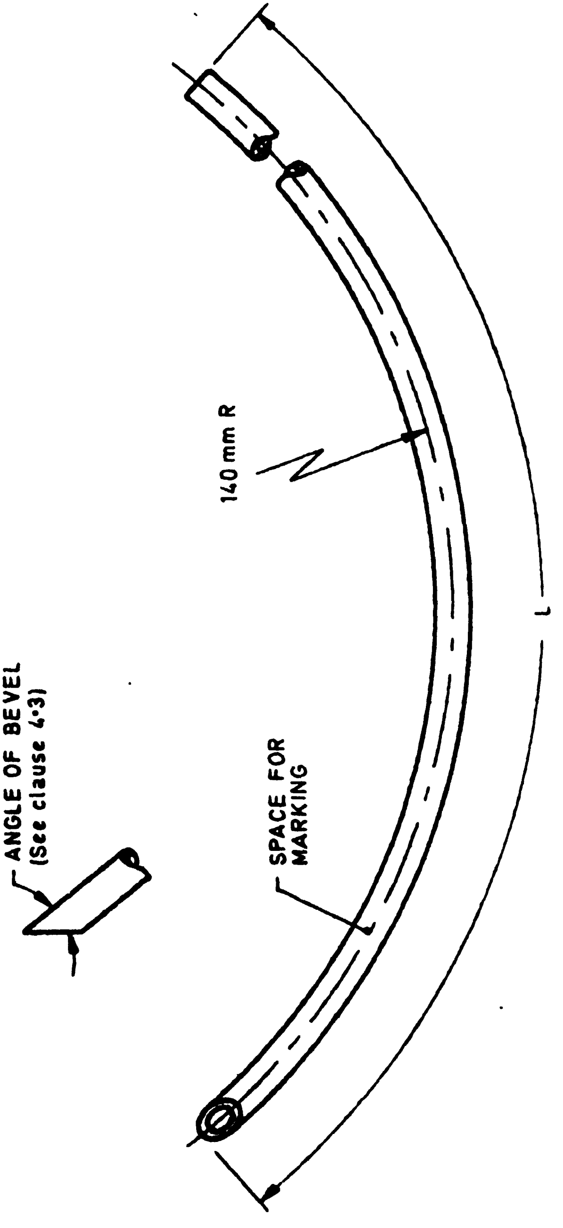

FIG. 1 ENDOTRACHEAL TUBE — PLAIN

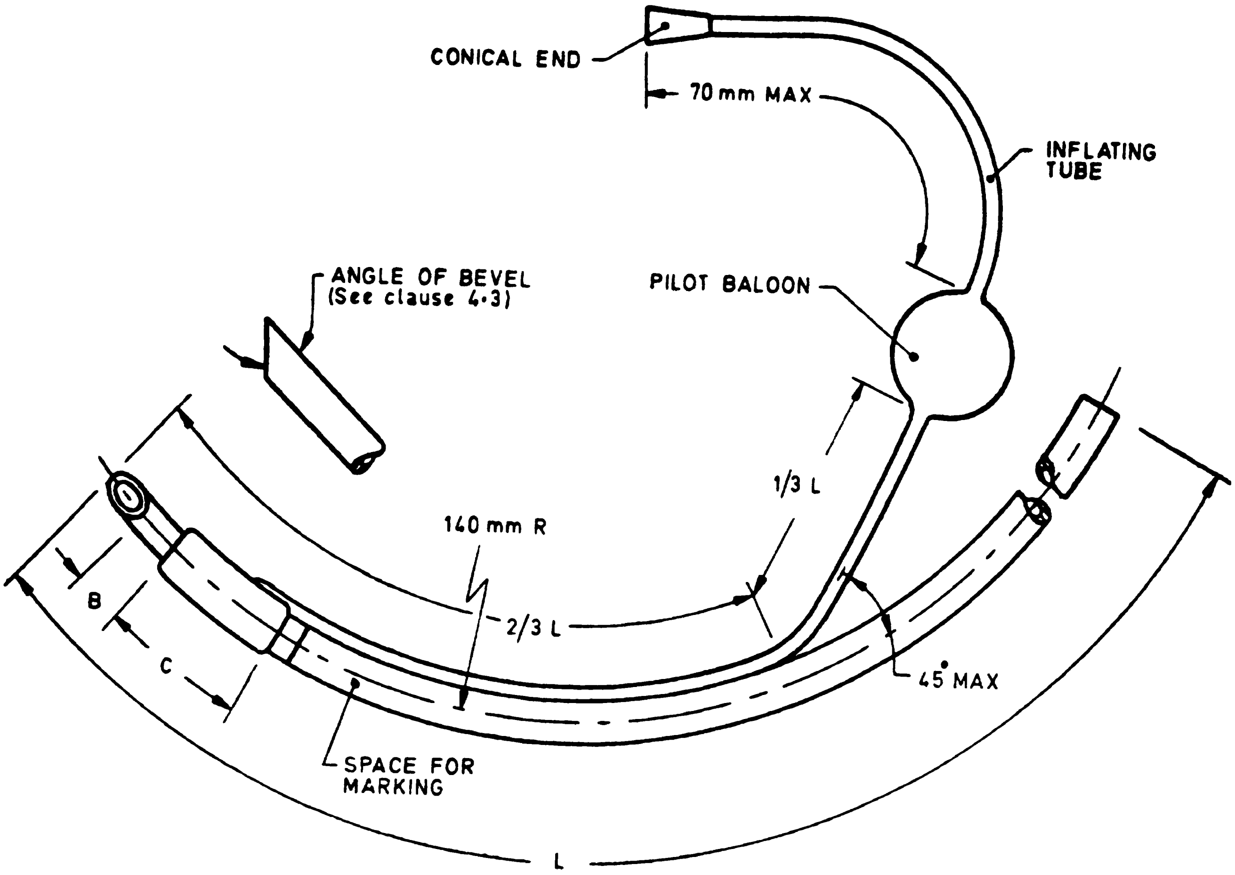

Fig. 2 Oral Endotracheal Tube — Cuffed

TABLE 1 REQUIREMENTS OF NATURAL RUBBER COMPOUND

(*Clause* 3.1)

Sl No.	Test	Requirements		Method of Test
		Before Ageing	After Accelerated Ageing in an Air-Oven at 70 ± 1°C for 168 Hours in Accordance with IS : 3400 (Part IV)-1960*	
(1)	(2)	(3)	(4)	(5)
i)	*Tubes*			
	a) Tensile strength	5·5 MN/M^2 (56 kgf/cm^2 approx), *Min*	Not less than 70 percent of the value obtained before ageing	In accordance with IS : 3400 (Part I)-1965† using dumb-bell test pieces
	b) Elongation at break	200 percent, *Min*	Not less than 50 percent of the value obtained before ageing	
	c) Hardness for sizes 2·5, 3·0, 3·5 and 4·0	84 ± 4 IRHD	Not more than 5 IRHD more than the value obtained before ageing	In accordance with IS : 3400 (Part II)-1964‡
	d) Hardness for sizes 4·5 and over	76 ± 4 IRHD		
ii)	*Cuffs*			
	a) Tensile strength	10·3 MN/m^2 (105 kgf/cm^2), *Min*	Not less than 80 percent of the value obtained before ageing	In accordance with IS : 3400 (Part I)-1965† using dumb-bell test pieces
	b) Elongation at break	600 percent, *Min*	Not less than 80 percent of the value obtained before ageing	

*Method of test for vulcanized rubber: Part IV Accelerated ageing.

†Method of test for vulcanized rubber: Part I Tensile stress-strain properties.

‡Method for determining the vulcanized rubber : Part II Hardness of vulcanized rubber.

4.2 The radius of curvature for both oral and nasal tube shall be 140 mm.

4.3 Nasal tubes of size 5·0 or less and all oral tubes shall have the angle of bevel of about 45° in relation to the axis of the tube. Nasal tube of size 5·5 and greater shall have the angle of bevel of about 30° in relation to the axis of the tube.

4.4 Unless otherwise specified by the purchaser, the bevel of oral tubes shall have the opening facing to the left when the tube is viewed from the concave aspect, in the vertical plane, bevel-end uppermost. Nasal tubes may have the bevel facing in either direction.

4.5 The distance from the patient end of the inflating portion of a permanently bonded cuff to the nearest edge of the bevel for endotracheal tubes of size 6·5 and larger (*see* Fig. 2, Dimension *B*) shall be between 10 and 13 mm. The inflating length of the cuff (*see* Fig. 2, Dimension *C*) shall be in accordance with Table 2.

TABLE 2 DIMENSIONS OF ENDOTRACHEAL TUBES

(All dimensions in millimetres)

DESIGNATED SIZE (NOMINAL INTERNAL DIAMETER)	MINIMUM LENGTH OF TUBE (*see* *L* IN FIG. 1 AND 2)		EFFECTIVE LENGTH OF CUFF* (*see* *C* IN FIG. 2)	WALL THICKNESS OF TUBE (TOL : $^{+0\cdot2}_{-0\cdot1}$)	
	Oral	Nasal		Oral	Nasal
(1)	(2)	(3)	(4)	(5)	(6)
2·5	140	—	—	0·6	—
3·0	160	—	—	0·6	—
3·5	180	—	—	0·6	—
4·0	200	—	—	0·6	—
4·5	220	—	—	0·6	—
5·0	240	—	—	1·0	—
5·5	250	270	—	1·2	0·8
6·0	260	280	—	1·2	0·8
6·5	280	290	30 ± 5	1·2	0·8
7·0	290	300	35 ± 5	1·2	1·0
7·5	300	310	35 ± 5	1·4	1·0
8·0	310	320	35 ± 5	1·4	1·2
8·5	320	330	35 ± 5	1·6	1·2
9·0	330	340	35 ± 5	1·6	1·4
9·5	340	350	35 ± 5	1·6	—
10·0	350	360	35 ± 5	1·6	1·4
10·5	350	360	35 ± 5	1·6	—
11·0	350	360	35 ± 5	1·6	1·5

*Provision has not been made for dimension *C* for cuffed endotracheal tubes of sizes 6·0 and less. Although cuffs are sometimes required for sizes 5·0, 5·5 and 6·0, they are seldom required for sizes of 4·5 and less.

4.6 The inflating tube, if fitted, shall have an external diameter of not more than 3·0 mm and shall be situated on the concave aspect of the parent tube. The inflating tube shall not encroach on the lumen of the endotracheal tube. The dimensions of the inflating tube shall be in accordance with Table 2. If the inflating tube be attached externally to the parent tube, the attachment may be in such a manner that the inflating tube may be partly stripped off from the parent tube, if required.

4.7 The free end of the inflating tube may be open or sealed with an appropriate plug or valve. Where the end is open, it shall have a female conical shape and capable of fitting to the male conical fitting with a 6-percent taper (Luer) in accordance with IS : 3234-1965*. Alternatively, the inflating tube shall be fitted with a mount having a female conical fitting with a 6-percent taper (Luer) in accordance with IS : 3234-1965*.

4.8 Angle between the inflating tube and the machine end of the parent tube at the separating point (*see* Fig. 2) shall not exceed 45°.

5. SIZE DESIGNATION

5.1 The size of the endotracheal tube shall be designated by a number giving the nominal internal diameter expressed in millimetres.

6. WORKMANSHIP AND FINISH

6.1 The endotracheal tubes shall be smooth externally and internally. The cuffs shall have a smooth surface.

6.2 The end of the tube at the bevel shall be round and there shall not be a sharp point at the tip of the bevel.

6.3 The cuff, if fitted, shall be capable of reasonably symmetrical expansion, when the cuff is inflated with air to a diameter of 1·5 times the external diameter of the tube.

6.4 The inflating tube shall be attached to the parent tube and shall join the cuff in such a manner as to ensure that there is no undue projection to interfere with the clinical use of the tube.

6.5 The inflating tube may be provided with a pilot balloon (*see* Fig. 2). The pilot balloon when deflated shall lie flat and shall be so constructed as to give adequate indication of the inflation of the cuff at the pressure required to distend the cuff to one and a half times of external diameter of the tube.

7. MARKING

7.1 Marking Materials — Marking materials used on endotracheal tubes shall be of a contrasting colour, shall be compatible with the human tissue with which the tubes are intended to be used and shall resist anaesthetic agents and agents commonly used in cleaning and sterilizing.

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*Specification for conical fitting for hypodermic syringes, needles and other medical equipment, Luer type.

7.2 The endotracheal tube shall be legibly and indelibly marked as follows:

- a) The word 'Oral' or 'Nasal', as appropriate, on the tubes with cuff;
- b) Size number in accordance with **5**;
- c) The name or trade-mark of the manufacturer; and
- d) Country of origin.

7.3 Disposable endotracheal tubes shall be clearly marked 'Use Once' or in a manner agreed to between the purchaser and the supplier.

7.3.1 The endotracheal tube may also be marked with the ISI Certification Mark.

Note — The use of the ISI Certification Mark is governed by the provisions of the Indian Standards Institution (Certification Marks) Act, and the Rules and Regulations made thereunder. Presence of this mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard, under a well-defined system of inspection, testing and quality control during production. This system, which is devised and supervised by ISI and operated by the producer, has the further safeguard that the products as actually marketed are continuously checked by ISI for conformity to the standard. Details of conditions, under which a licence for the use of the ISI Certification Mark may be granted to manufacturers or processors, may be obtained from the Indian Standards Institution.

8. PACKING AND STORAGE

8.1 The endotracheal tubes shall be packed as agreed to between the purchaser and the supplier. The tubes shall be stored in a cool dark place, preferably in a rigid container in which the tubes are not likely to be subjected to mechanical damage. The number of tubes kept in one container shall be limited in order to avoid deformation of any tube either by crushing or by the formation of kinks. The tubes shall not be allowed to come into contact with oil-based antiseptic phenols and their derivatives, petroleum-based grease, petroleum spirit paraffin (kerosene) or other related organic products since all these materials are extremely harmful to rubber.

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